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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,965	03/25/2004	Raghunath Vitthal Chaudhari	A36200-PCT-USA-A; 066123.	7075
21003	7590	06/13/2006	EXAMINER OH, TAYLOR V	
BAKER & BOTTS 30 ROCKEFELLER PLAZA 44TH FLOOR NEW YORK, NY 10112			ART UNIT 1625	PAPER NUMBER

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Applicant(s)</b>	
	CHAUDHARI ET AL.	
	<b>Application No.</b>	<b>Art Unit</b>
	10/808,965	1625
	<b>Examiner</b>	
	Taylor Victor Oh	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 May 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 and 11-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____                                                             | 6) <input type="checkbox"/> Other: _____                                    |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/25/06 has been entered.

The Status of Claims:

Claims 1-8,11-23 are pending.

Claims 1-8, 11-23 have been rejected.

**DETAILED ACTION**

1. Claims 1-8, 11-23 are under consideration in this Office Action.

**Priority**

2. it is noted that this application is a continuation of PCT/IB03/06202 filed 12/26/2003.

**Drawings**

3. None.

**Specification**

The disclosure is objected to because of the following informalities:

On the line 4, paragraph (0022) on page 7 , the chemical term “ dioxin” is recited. The chemical term is mis-spelled. Appropriate correction is required.

### ***Claim Objections***

Claim 17 is objected to because of the following informalities:

In claim 17, the chemical term “ dioxin” is recited. The chemical term is mis-spelled. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 5 and 6 , the phrase “alkyl group containing ” is recited. This is vague and indefinite. The term “ containing ” would mean that there are other additional

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components besides the only alkyl group. The examiner recommend to change the the term “ containing” to “having”. Therefore, an appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an acid catalyst , such as, p-toluene sulphonic acid , hydrochloric acid , resin does not reasonably provide enablement for all the acidic catalysts known in the field of chemistry. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all the catalysts unrelated to the invention commensurate in scope with these claims. Furthermore, the instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation, citing *Ex Parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,

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- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

In the instant case, the claim encompasses various acidic catalysts. However, applicants' specification provide only particular exemplified catalyst compounds (p-toluene sulphonic acid , hydrochloric acid , resin as shown in the examples 11-13). Furthermore, the catalyst compositions represent an unpredictable aspect in the art of organic chemistry . See *Exparte Sizto*, 9 USPQ2d 2081 (Bd. Of App. And Inter. March 1988). Thus, the specification herein have failed to provide sufficient working examples to support the use of all kinds of acidic catalysts. Therefore, an appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 11-12, and 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cesa et al (EP 0144118) in view of Nicholson et al (US 5,744,650).

Cesa et al discloses the preparation of 2-hydroxy carboxylic acid by the reaction of enol acylates with carbon monoxide and organic hydroxyl compounds to produce esters hydrolysable to hydroxy acids (see page 1 ,lines 1-9) in the following examples below:

EXAMPLE 11

0.50 mmoles vinyl acetate and 2.5 mmoles methanol were charged into a 71 cc stainless steel bomb equipped with a glass liner and a Teflon coated stir bar. 10.9 mole percent, based on vinyl acetate, of a catalyst comprising  $\text{Pd}(\text{P}\phi_3)_4$ , was added. 0.05 mmoles toluene was included as an internal standard. Five milliliters of tetrahydrofuran as a solvent were also included in the reaction system. The reaction mixture was charged under argon. The bomb was sealed and carbon monoxide at a pressure of 850 psi (at room temperature) was charged to the bomb, and the bomb was heated to 100°C and allowed to react for 43.5 hours with stirring. At the termination of the reaction, the reaction products were analyzed by gas chromatography and it was found that methyl 2-acetyloxypropanoate was produced in a yield of 35.1 percent.

(see example 11 , lines 15-29).

Furthermore, according to Example 16 , methyl 2-acetyloxypropanoate was hydrolyzed to lactic acid by adding it with 2 N aqueous HCl solution; the reaction mixture was allowed to cool to room temperature (see example 16 ,lines 21-26).

Usually, the reaction is carried out with a solvent. The solvent selected from the group consisting of tetrahydrofuran , benzene, acetonitrile, tetrahydrofuran (see page 5 ,lines 30-37). After the reaction is complete, the ester products can be recovered from the reaction system by vacuum distillation (see page 7 ,lines 15-17).



In addition, the reactant concentrations can vary widely and are not critical. The ratio of hydroxy reactant to the enol ester is usually no greater than 10/1 on a molar basis (see page 5 ,lines 21-23); the amount of catalyst is between 0.01 and 100 mole percent based on the enol ester (see page 5 ,lines 27-28).

The instant invention, however, differs from the prior art in that the claimed hydrolysis catalyst is recycled for the hydrolysis step is unspecified; the claimed organic ligand contains pyridine and triethyl amine.

Nicholson et al discloses a general carbonylation process (see col. 46 ,lines 53-54) in which one or more reactants are reacted in a solvent selected from the group of acetone, methyl ethyl ketone, toluene, and tetrahydrofuran (see col. 34 ,lines 46-50) in the presence of carbon monoxide and palladium-organopolyphosphite ligand (see col. 7 ,lines 31-32) containing a halogen , pyridine , triethyl amine ,and etc (see col. 8 ,lines 7-13) to produce a reaction product fluid (see col. 3 , lines 21-26) , wherein the desired product can be separated via distillation (see col. 36 , lines 29-30); furthermore, Nicholson et al has offered guidance with the remaining non-volatilized catalyst containing liquid reaction mixture which is recycled back to the reactor (see col. 36, lines 33-35).

With respect to the unspecified recycling step for the hydrolysis catalyst, the Cesa et al reference is silent. However, the Nicholson et al reference does teach that

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the recycling step for the carbonylation catalyst is a well-known procedural aspect for its economical benefit; by the same token, it is quite possible to recycle the hydrolysis catalyst used in the Cesa et al process for the sake of the economical process.

Cesa et al does disclose the preparation of lactic acid by the reaction of enol acylates with carbon monoxide and the organic hydroxyl compounds to produce esters hydrolysable to hydroxy acids. Similarly, Nicholson et al expressly teaches that it is possible to apply the recycling step of the catalyst during the carbonylation process (see col. 10 ,lines 32-35). The Cesa et al process is related to the carbonylation process and the hydrolysis process, whereas the Nicholson et al is concerned with the carbonylation process plus the recycling step of the catalyst; from this, there is a teaching of an equivalence between them with respect to the common carbonylation process. Therefore, it would have been obvious to the skilled artisan in the art to be motivated to incorporate the Nicholson's et al recycling step into the Cesa et al process in order to economize the overall process because the skilled artisan in the art would expect such a combination to be successful and economical as the guidance(see col. 36, lines 33-35) shown in the Nicholson et al process.

### **Applicants' Argument**

Applicants argue the following issues:

- a. Neither Cesa nor Nicholson disclose the use of a nitrogen or oxygen containing organic compound as a ligand to increase catalytic activity;

- b. Nicholson teaches away from phosphine catalysis in a CO environment.

Applicants' arguments have been noted, but the arguments are not persuasive.

First, regarding the first and second arguments, the Examiner has noted applicant's argument. However, the claims are not directed to the increased catalytic activity of the claimed process using nitrogen or oxygen containing organic compounds, but the claims are more directed to the process for preparing a 2-hydroxy carboxylic acid using a reusable catalyst. Furthermore, Cesa et al expressly teaches that when using  $(\text{P}^{\text{t-Bu}})_2\text{PdCl}_2$  or  $\text{Pd}(\text{P}^{\text{t-Bu}})_4$  catalyst, other palladium compounds,  $\text{CH}_3\text{CN}$  or/ and tetrahydrofuran can be used together during the reaction process (see col. 4, lines 30-37); from this, there is still a teaching for the organic ligand surrounding palladium catalyst. Moreover, Nicholson et al expressly discloses the general carbonylation process (see col. 46, lines 53-54) in which one or more reactants are reacted in a solvent selected from the group of acetone, methyl ethyl ketone, toluene, and tetrahydrofuran (see col. 34, lines 46-50) in the presence of carbon monoxide and palladium-organopolyphosphite ligand (see col. 7, lines 31-32) containing a halogen, pyridine, triethyl amine, and etc (see col. 8, lines 7-13) to produce a reaction product fluid (see col. 3, lines 21-26). Therefore, both prior art are still relevant to the claimed invention.

Also, concerning phosphine catalysis in a CO environment, the primary Cesa prior art process does point out that when a metal is complexed with a phosphine, the

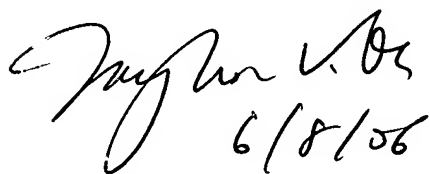
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carbonylation and the hydrolysis do take place effectively in the CO environment (see col. 5 ,lines 18-29). Therefore, applicants' arguments are irrelevant to the issue of the invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
6/8/06